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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,309	10/15/2001	Tony Cruz	033352-010	4565

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/15/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,309

Applicant(s)

CRUZ ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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This is a new ground of restriction requirement. The previous restriction to the current invention mailed 8 April 2003 (Paper No. 15) has been vacated. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 10-14, drawn to a polypeptide and a pharmaceutical composition comprising the polypeptide thereof, classified in class 530, subclass 300, and class 514, subclass 2.
- II. Claims 7-9, drawn to an antibody that binds to the polypeptide, classified in class 530, subclass 387.1.
- III. Claims 15-23 and 29-33, drawn to a of treating a disease state comprising administering to a patient the polypeptide or an antibody that binds the polypeptide, classified in class 514, subclass 2, class 530, subclass 300, 388.1 and 389.1, and class 424, subclass 184.1.

The inventions are distinct, each from the other for the following reasons:

Inventions I and II are patentably distinct from one another because of the materially different structures of the compounds claimed. Invention I (polypeptide) and Invention II (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Invention I (polypeptide) and Invention II (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Inventions I and III, and, Inventions II and III are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, In the instant case, the polypeptide can be used in proteinchip array to investigating signal transduction pathway, and the antibody can be

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immobilized on the chip-gold surface in surface plasma resonance technique in order to detecting real time protein-protein interaction, for example.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Additional election

It should be noted that this is not a species election but a part of the restriction requirement. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed 37 C.F.R. 1.143). In the response, applicant is to indicate (1) the elected group and indicate (2) the further election as required below.

Where Group I is elected, under 35 U.S.C. 121, applicant is also required to elect one peptide sequence by sequence identifier and identify the claims readable thereon from SEQ ID NOs: 26, 81, 73, 74, 75, 76, 77 and 78 from claims 1-2 and 5 since each sequence structurally differs from one another. Applicant should identify the elections.

Where Group II is elected, applicant is required under 35 U.S.C. 121 to elect one antibody which binds to the polypeptide of SEQ ID NO: 26 or 81 or 73 or 74 or 75 or 76 or 77, or 78 or 83 by sequence identifier and identify the claims readable thereon from claim 7 since each sequence structurally differs from one another. Applicant should identify the elections.

Where Group III is elected, applicant is also required to specify the election under 35 U.S.C. 121 of either (A) one polypeptide from SEQ ID NOs: 26, 81, 73, 74, 75, 76, 77, 78 and 83 by sequence identifier and identify the claims readable thereon from claims 15, 19, 23, 24, 28 and 29 since each sequence differs from one another in chemical and physical structure and biological activity; or (B) on antibody that binds to the polypeptide from SEQ ID NOs: 26, 81, 73, 74, 75, 76, 77, 78 and 83 thereof. Additionally, applicant is required to elect one particular disease or disorder (e.g., multiple sclerosis or Parkinson's disease or Alzheimer's disease in claim 17) from claim 17, 19, 21 and 28 since each disease or disorder state in the claims are

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different/distinct in its pathological mechanism and therapeutic treatment,. Applicant should identify the elections.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

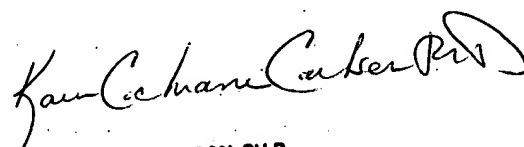
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Papers related to this application may be submitted by facsimile transmission to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1) and must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The telephone number assigned to Art Unit 1804 in the CM1 PTO Fax Center is (703) 308--4242 or 305-3014.

SWL

Samuel W. Liu, Ph.D.

May 5, 2003


KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER